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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,110

06/20/2005

Matthias Kraemer

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EXAMINER

D'ANGELO, MICHAEL J

ART UNIT

PAPER NUMBER

3735

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,110	Applicant(s) KRAEMER, MATTHIAS	
	Examiner MICHAEL D'ANGELO	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 10-14, 16, and 21-24 is/are rejected.
- 7) ☒ Claim(s) 4,6-9,15 and 17-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/17/2006;03/15/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: line 2 recites "blood a portion" which should read --a blood portion--. Appropriate correction is required.
2. The claims include reference characters which are enclosed within parentheses. The use of reference characters is considered as having no effect on the scope of the claims. Since the reference characters are not afforded patentable weight, the reference characters enclosed within parentheses apparently should be deleted from the claims. Correction is requested.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 1 and 10 recite the limitation "the blood flow rate Q_F " in line 1. There is insufficient antecedent basis for this limitation in the claim.
6. Claims 1 and 10 recite the limitations "the value Y_A " and "the value Y_V " in lines 9 and 10 respectively. There is insufficient antecedent basis for this limitation in the claim.

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7. Claims 1 and 10 recite the limitations "the rate dX_A/dt " and "the rate dX_V/dt " in lines 15 and 16 respectively. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 2 recites the limitation "the blood flow rate Q_B " in line 2. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 15 recites the limitation "the method according to claim 14" in line 1. There is insufficient antecedent basis for this limitation in the claim.

10. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 23 recites the broad recitation in a blood vessel, and the claim also recites an arteriovenous fistula or a shunt which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 1-9 are rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter because these are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to another statutory class (such as a particular machine). See *Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (quoting *Benson*, 409 U.S. at 70); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978) (citing *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)). See also *In re Comiskey*, 499 F.3d 1365, 1376 (Fed. Cir. 2007) (request for rehearing en banc pending). The recitation of an arterial and venous line is not sufficient enough to tie the method claims above to another statutory class, nor do these claims recite or imply a physical transformation of any sort.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-2, 5, 10, 16, and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Gotch et al. (EP 0 928 614 A1).

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15. **Regarding claim 1**, Gotch discloses a method of determining the blood flow rate Q_F in a blood-carrying line (abstract), of which blood a portion is branched off at a first location through an arterial line and through a venous line and is returned at a second location (view figure 1, abstract), whereby a physicochemical variable Y of the blood (abstract), which is constant over a period of time for a measurement interval (it is inherent that any variable will be constant for some period of time, no matter how small), is determined in the arterial line as having the value Y_A (paragraph 33, lines 4-11) and is determined in the venous line as having the value Y_V (paragraph 34, lines 3-8), the net rate dX/dt of a variable X derived from the physicochemical variable Y into or out of the blood-carrying line during the measurement interval is determined from the values Y_A and Y_V as the difference between the rate dX_A/dt removed through the arterial line and the rate dX_V/dt supplied through the venous line (paragraph 69), and the net rate dX/dt is used to determine the blood flow rate Q_F (paragraph 69, lines 5-7).

16. **Regarding claim 10**, Gotch discloses an arterial line branching off from the blood line with which blood is removed from the line (arterial line -76, view figure 1), a venous line opening into the blood line with which blood is supplied to the line (venous line-64, view figure 1), an arterial measurement means and a venous measurement means for determining a physiochemical variable Y of the blood in the arterial line with the value Y_A (detector-34, paragraph 33) and in the venous line with a value Y_B (detector-46, paragraph 34), these variables being constant over a period of time for a measurement interval (it is inherent that any variable will be constant for some period of time, no matter how small), An analyzer unit connected to the arterial and venous

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measurement means, being suitable for determining the net rate dx/dt of a variable X derived from a variable Y into or from the blood line during the measurement interval as the difference between the rate dX_A/dt and the rate dX_V/dt from the values Y_A and Y_V (paragraph 69, comparator-54), and it is also suitable for using the net rate dx/dt to determine the blood flow rate Q_f (paragraph 69, line 5-7).

17. **Regarding claim 2**, Gotch discloses that the blood flow rate Q_b is determined in the arterial line and in the venous line for the determination of the rate removed dX_A/dt and the rate supplied dX_V/dt (equation 4 utilizes the flow rate in the arterial and venous lines (i.e. Q_d) for determining the supplying and removing rates (dialysance)).

18. **Regarding claims 5 and 16**, Gotch discloses a physiochemical variable Y is the concentration c of a substance in blood, and X is the quantity C of the substance in the carrying line (paragraph 68, lines 1-8, it is inherent that with a known initial concentration and volume a quantity of a substance C is known as well).

19. **Regarding claim 21-24**, Gotch discloses that the arterial and venous lines are part of an extracorporeal blood circulation system (view figure 1, it is inherent that the device of Gotch performs the procedure outside the body), that the blood treatment device is a hemodialysis device (paragraph 22, lines 1-2), that the blood flow rate Q_F , to be determined is the blood flow in a blood vessel (abstract), in particular an arteriovenous fistula or shunt, in a patient (abstract), and that the device has a display unit suitable for displaying the blood flow rate (paragraph 69, line 1).

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Determining the scope and contents of the prior art.
Ascertaining the differences between the prior art and the claims at issue.
Resolving the level of ordinary skill in the pertinent art.
Considering objective evidence present in the application indicating obviousness or nonobviousness.

22. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gotch et al. (EP 0 928 614 A1) as applied to claim 1 above, and further in view of Polaschegg (US 4,894,164).

23. **Regarding claim 3**, Gotch fails to disclose that the variable Y is a thermal energy per unit volume and the variable X is the thermal energy of the blood.

24. However, Polaschegg discloses that the variable Y is a thermal energy per unit volume and the variable X is the thermal energy of the blood (claim 9).

25. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the dialysis device of Gotch to include measuring a thermal energy

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per unit volume and a thermal energy as taught by Polaschegg in order to maintain a patients internal body temperature during a dialysis procedure.

26. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotch et al. (EP 0 928 614 A1) as applied to claim 10 above, and further in view of Krivitski et al. (US 5,685,989).

27. **Regarding claims 11 and 12**, Gotch fails to disclose a means for detecting or adjusting the blood flow rate Q_B wherein the means is a flow sensor.

28. However, Krivitski discloses a means for detecting or adjusting the blood flow rate Q_B wherein the means is a flow sensor (column 6, lines 58-67 and column 7, lines 1-9).

29. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the dialysis device of Gotch to include a means for detecting or adjusting the blood flow rate Q_B wherein the means is a flow sensor as taught by Krivitski in order to obtain an accurate blood flow measurement.

30. **Regarding claim 13**, Gotch discloses a control unit (control unit-230), which is used for setting a delivery rate of a blood pump (pump-78), which is situated in the arterial line or venous line and is connected to the analyzer (comparator-54, view figure 1).

31. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gotch et al. (EP 0 928 614 A1) as applied to claim 10 above, and in view of Krivitski et al. (US 5,685,989) and further in view of Polaschegg (US 4,894,164).

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32. **Regarding claim 14**, Gotch's invention as modified by Krivitski fails to disclose that the variable Y is a thermal energy per unit volume and the variable X is the thermal energy of the blood.

However, Polaschegg discloses that the variable Y is a thermal energy per unit volume and the variable X is the thermal energy of the blood (claim 9).

33. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a hemodialysis apparatus similar to that of Gotch, as modified by Krivitski, with using a variable Y that is a thermal energy per unit volume and a variable X that is the thermal energy of the blood as taught by Polaschegg in order to maintain a patients internal body temperature during a dialysis procedure.

Allowable Subject Matter

34. Claims 4, 6-9, 15, and 17-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 4, 6-9, 15, and 17-20 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

35. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record fails to teach or suggest using the formulas of the claims above for calculating physiological parameters.

Conclusion

36. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6610027, US 5518623, US 5716531 and US 2004/0073153 are directed toward measuring a blood flow rate in a blood vessel using a hemodialysis method and apparatus similar to that of the present application.

37. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL D'ANGELO whose telephone number is (571) 270-7112. The examiner can normally be reached on Monday-friday 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/MD/
Examiner, Art Unit 3735